Pediatric Protocol Checklist for Original IDEs or IDE Supplements

The following parameters should be reviewed for protocols which include a purely or partially pediatric (i.e., birth to 21 years) population. Please also consult the guidance "Premarket Assessment of Pediatric Medical Devices" for more details at http://www.fda.gov/cdrh/mdufma/guidance/1220.html.

Report of Prior Investigations

1. Does the following testing support initiation of the clinical trial in the specified pediatric population?
    - Preclinical YES:____ NO_____
    - Bench/animal YES:____ NO:_____
    - Prior adult clinical testing, as appropriate YES:____ NO:_____

Comments:_____
_____
_____

2. Does the following testing support initiation of the clinical trial in the specified pediatric population?
    - Preclinical* YES:____ NO_____
    - Bench/animal* YES:____ NO:_____
    - Prior adult clinical testing, as appropriate YES:____ NO:_____

*For preclinical, bench and/or animal model determinations, how were the studies done to approximate the pediatric population?

- Were age-matched animals used? If so, describe how the age approximation was determined.

- Structural/anatomical considerations
    - Was implant size for initial placement considered?
    - Did sizing consideration include gradual growth of the individual?

- Did preclinical testing include safety and effectiveness determinations in models designed to reproduce the clinical condition?
    - Were the animals induced chemically or biologically to recapitulate the condition? If so, identify the system used.
    - If immune responses are possible, were immunological studies conducted with age-correlated organisms?

Comments:_____
_____
_____

3. Has adequate background information on the pediatric population with the condition to be treated or diagnosed, including numbers of pediatric patients affected and the pediatric subpopulation being evaluated, been provided?

   YES: ___ NO: ___

Comments:
_____
_____

4. Have other available treatment(s) for this population been adequately discussed?

   YES: ___
   NO: ____

Comments:
_____
_____

Investigational Plan – Protocol

4. A)Identification of population: Has the patient population been defined (i.e., newborn, infant, child, adolescent)? Are there subpopulations within these groups that should be defined (e.g., low birth weight, preterm, neonate, infant, school age, preadolescent, adolescent)?

   YES:___
   NO: ___

Comments:_____
_____

4 b) Has appropriate long-term follow-up been considered?

   YES ___
   NO ____

Comments:
_____
_____

5. Have the inclusion/exclusion criteria for the identified pediatric population been adequately refined?

   YES: ___
   NO: ___

Comments:

_____
_____

6. Are there adequate safeguards in place within the protocol, including:

    - Availability of pediatric expertise throughout the trial;
    - Case report forms;
    - An appropriate schedule for treatment and follow-up;
    - Plan for reporting to a Clinical Events Committee or Data Safety Monitoring Board, guardian(s)' accessibility to study investigators and/or coordinators in the event of any concerns; and
    - Emergency preparedness plan to capture and act on adverse events (device-related or not) in a timely fashion?

    YES: ___
    NO: ___
Comments:
_____
_____

Investigational Plan – Risk Analysis

7. Has the sponsor included an adequate risk/analysis with specific reference to the identified pediatric population? When assessing risk, the following critical factors should be considered:
    - age and degree of physiological and psychological maturity of the child;
    - nature and natural history of the clinical condition to be treated; (e.g., genetic)
    - presence of complicating clinical conditions;
    - safety and effectiveness of the device that may have been demonstrated in older patients, or that is expected on the basis of other pre-clinical testing, clinical investigations or clinical use;
    - likely duration of device use and its impact on the growth and development of the child.

    YES: ___
    NO: ___
    Comments:_____
    _____
    _____

Investigational Plan – Description of the Device

8. In designing the device, has the sponsor considered the following factors, if applicable, with respect to device-patient interaction: impact of size (height, weight, surface area, body mass, pubertal stage), growth and development (e.g., growth plates closed for specific bones involved), and other relevant anatomical and physiological factors?

   YES: ___
   NO: ___
   Comments:_____
   _____
   _____

Investigational Plan – Informed Consent

9. Have all of the elements of informed consent, as identified in 21 CFR 50.25, been adequately addressed in the informed consent document provided, particularly with respect to the specified pediatric population? Has the sponsor addressed in their investigational plan the additional safeguards required by 21 CFR Part 50 Subpart D ("Additional Safeguards for Children in Clinical Investigations") as bulleted here and discussed in more detail in the guidance "Premarket Assessment of Pediatric Medical Devices" at http://www.fda.gov/cdrh/mdufma/guidance/1220.html?

   a. Assessment of whether investigation involves minimal risk or greater than minimal risk
   b. Assessment of whether investigation has prospect of direct benefit to patient or may yield generalizable knowledge
   c. Assessment of whether investigation that is not otherwise approvable may present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children
   d. Requirements for permission by parents or guardians and for assent by children
   e. Inclusion of children who are wards of the state in investigations

   YES: ___
   NO: ___
   Comments:_____
   _____
   _____

10. Has the sponsor indicated that pediatric assent will be sought, if age-appropriate? Has the sponsor specifically indicated that informed consent will be sought from all or one of the patient's guardian(s) and provided a justification for their plan for consent? (Consider issues such as emancipated minors, legal guardian, foster parent, age of understanding). For further guidance, refer to 21 CFR Part 50 Subpart D ("Additional Safeguards for Children in Clinical Investigations").

YES: ___
NO: ___
Comments:
_____
_____

11. Has the sponsor indicated what compensation if any is provided to the guardian(s) or patients? Is the compensation plan appropriate?

YES: ___
NO: ___
Comments:
_____
_____

Required signatures:

Medical Officer: _____

Lead Reviewer: _____